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Extracorporeal Shock Wave Lithotripsy (ESWL) for Biliary Stones: A Nationwide Survey in Japan

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Summary

To assess the current status of extracorporeal shock wave lithotripsy (ESWL) for the treatment of gall-stones in Japan, we conducted a nationwide survey by sending a questionnaire to 251 institutions using this therapy. Replies were obtained from 50 institutions. The use of ESWL was investigated over the period from its introduction up to October 1992.

ESWL was performed on 2,760 of 10,058 patients with gallstones (27.4%). The stones were completely pulverized in 1,021 of these 2,760 patients (37.0%). Complete disappearance was limited to single gallstones less than 20 mm in maximum diameter. A comparison in the number of ESWL sessions revealed no significant difference between the patients with and without a good response.

Choledocholithiasis was resolved completely in 44.0% of 157 patients who underwent ESWL for this condition and intrahepatic stones were cured in 18.7% of 32 patients. Therefore, ESWL may be a useful form of conservative therapy for biliary calculi.

Introduction

In 1882, Langenbuch initially performed cholecystectomy for the treatment of gallstones, and since then surgical treatment had been the primary means of handling this disease for over a century. Recently, oral litholytic therapy has been promoted as non-surgical treatment for gallstones.

In 1986, a group at Munich University first applied extracorporeal shock wave lithotripsy (ESWL) for the treatment of gallstones, a development which attracted keen medical interest[1]. In Japan, an ESWL system was first introduced at the University of Tokyo in 1987 and gallstones were then treated using this method. ESWL rapidly became more popular in Japan and a consensus has recently been reached on its clinical value and indications.

We conducted a nationwide survey to assess the present status of ESWL in the treatment of cholelithiasis in Japan, with the intention of reporting the results of this survey at the 5th Meeting of

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the Japan Society of Shock Wave Therapy.

Subjects and Methods

A questionnaire was sent to a total of 251 institutions with ESWL systems as of October 1992. Institutions exclusively treating urological patients and those which only had an ESWL system for ureteric calculi were excluded from the study. The status of ESWL was investigated from the time of its introduction up to October 1992. Questions covered the following topics.

(1) The percentage of patients treated by ESWL among all those with gallstones.
(2) The outcome of ESWL (classified by the number of stones, the size of the stones, and the number of ESWL sessions).
(3) Concomitant use of oral litholytic therapy.
(4) Methods of achieving complete dissolution of gallstones.
(5) Application of ESWL for the treatment of intrahepatic and common bile duct stones.

Replies were collected from 50 institutions, so the recovery rate was about 20%. The rate was probably low because of a Ministry of Health and Welfare (MHW) directive in 1992 that ESWL therapy was only approved at institutions regularly employing at least two physicians for this purpose. Subsequently, quite a few institutions abandoned ESWL therapy.

The timing of the introduction of ESWL at the institutions investigated is shown in Table 1. The mean period of use was 2.4 years. Since 1990, laparo-scopic cholecystectomy has been widely adopted in Japan, and this has also reduced the number of institutions newly installing ESWL systems, although there were 3 institutions planning the introduction of ESWL after 1993.

For statistical analysis, the chi-square test was used.

Results

1) *Selection of therapy for gallstones*

A total of 10,058 patients with gallstones were treated at the 50 institutions investigated over a mean period of 2.5 years. ESWL was used for 27.4% of gallstone patients at the 50 institutions (Table 2). This frequency may be higher than the overall one, because data were probably collected from institutions actively employing ESWL.

2) *Outcome of ESWL*

The outcome of ESWL was classified as "effective" or "slightly effective," but since there was considerable variation in the criteria used by the individual institutions, only patients with complete disappearance of calculi were assessed in this report. Gallstones were completely pulverized in 1,021

Table 1 Introduction of ESWL

1987	2	(institutions)
1988	8	
1989	8	
1990	19	
1991	7	
1992	6	
1993	3	

Table 2 Treatment of Gallstones (Oct. 1987 to 1992)

ESWL	2,760	(27.4%)
Laparoscopic cholecystectomy	2,574	(25.8%)
Laparotomy (including mini-laparotomy)	4,706	(46.8%)
Others	18	(0.2%)
	10,058 patients	

Table 3 Outcome of ESWL for Gallstones

Complete resolution	1,021	(37.0%)
Effective	889	(32.2%)
Slightly effective	414	(15.0%)
No response	436	(15.8%)
	2,760 patients	

Table 4 Fragmentation by ESWL in Relation to the Number of Gallstones

	Complete disappearance	No response	
1 stone	783 (76.7%)	191 (43.2%)	*
2 stones	129 (12.6%)	146 (33.0%)	
3 or more stones	109 (10.7%)	105 (23.8%)	
	1,021 patients	442 patients	

* $p<0.01$

Table 5 Fragmentation by ESWL in Relation to Stone Size (maximum diameter)

	Complete disappearance	No response	
<10mm	249 (24.4%)	143 (32.4%)	*
11–20mm	553 (54.2%)	173 (39.1%)	
21–30mm	204 (20.0%)	109 (24.7%)	
>31mm	15 (1.5%)	17 (3.8%)	
	1,021 patients	442 patients	

* $p<0.01$

Table 6 Fragmentation by ESWL in Relation to the Number of ESWL Sessions

	Complete disappearance*	No response
1 session	306 (30.0%)	89 (20.1%)
2 or 3 sessions	391 (38.3%)	198 (44.8%)
4 or more sessions	324 (31.7%)	155 (35.1%)
	1,021 patients	442 patients

* The mean number of sessions until complete disappearance was 3.6 ± 2.2

of the 2,760 patients undergoing ESWL (37.0%) (Table 3).

Of these 1,021 patients with complete resolution of their stones, 783 (76.7%) had a solitary calculus. In contrast, multiple calculi were present in 56.8% of the patients in whom ESWL was ineffective. Thus, complete resolution was significantly more common for solitary gallstones than for multiple gallstones, and the presence of a solitary calculus is considered to be one of the important factors for achieving complete resolution of gallstones by ESWL (Table 4).

The stone was less than 20 mm in maximum diameter in 78.5% of the patients with complete resolution. Gallstones between 21 and 30 mm in maximum diameter accounted for 20% of those completely eliminated by ESWL, and stones larger than 31 mm made up only 1.5%. This result indicates that ESWL was generally used in compliance with the criteria[1] of SAUERBRUCH et al. The present investigation also indicated that complete resolution of gallstones was significantly more common when the calculi were less than 20 mm in diameter (Table 5).

In 306 of the 1,021 patients with complete resolution (30%), the gallstones were completely pulverized after only one session of ESWL, which was performed without anesthesia on an ambulatory basis. As long as ESWL was used for the appropriate indications, it produced complete resolution in most patients after up to 3 sessions (Table 6). However, a comparison between the patients with and without complete resolution revealed no significant difference in the number of ESWL sessions.

3) *Concomitant use of oral litholytic therapy and ESWL*

The type of gallstones was not determined in the present study. However, the calculi were probably often cholesterol stones, since a bile acid preparation was used concomitantly at the majority of the institutions.

Oral litholytic therapy was used before ESWL at 2/3 of the institutions and was used by 90% of

Table 7 Oral Litholytic Therapy Combined with ESWL

		Before ESWL	After ESWL
Not used		16 (32%)	5 (10%)
UDCA	300mg	6 (12%)	8 (16%)
	300–500mg	4	3
	600mg	18 (36%)	24 (48%)
	+CDCA	3	7 (14%)
Regimen varied depending on patients		3	3

them after ESWL. The patients were usually given ursodeoxycholic acid (UDCA) at dose of 600 mg/day (Table 7), but the combination of UDCA and chenodeoxycholic acid (CDCA) was used in some institutions.

4) *Method of achieving complete resolution of gallstones*

Few answers were given to this question. The most common reply was that strict selection of patients for ESWL is all that is necessary to achieve complete resolution. The specific ideas proposed were as follows:

(1) Select patients with a wide cystic duct (>3 mm) on endoscopic retrograde cholangiography (ERC).

(2) Limit ESWL to solitary calculi <20 mm in diameter which shows a CT value <100 HU and which are type Ia of Tsuchiya's ultrasound classification.

(3) Infuse isotonic saline into the cystic duct after selectively inserting an ERC tube to decrease the viscosity of bile. This procedure is thought to allow more efficient transmission of shock waves.

(4) Perform ESWL at a low energy with a higher number of shots initially, and repeat the ESWL sessions to make the fragments smaller.

5) *Application of ESWL for choledocholithiasis and intrahepatic calculi*

ESWL was applied for the treatment of choledocholithiasis at half of the institutions investigated, and in a total of 157 patients. For the treatment of intrahepatic calculi, ESWL was applied to

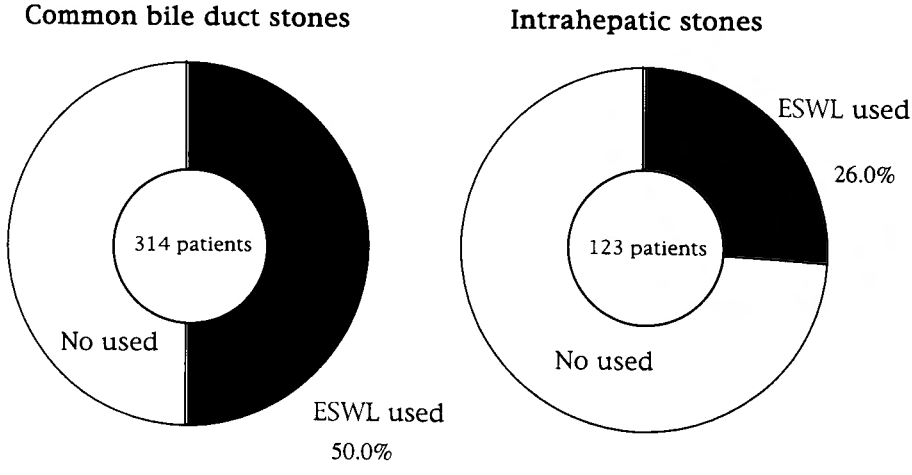

Fig. 1. Experience with ESWL in the treatment of common bile duct or intrahepatic stones.

Table 8 Outcome of ESWL for Common Bile Duct Stones and Intrahepatic Stones

	common bile duct stones	intrahepatic stones	total		
Very effective	69 (44.0%)	6 (18.7%)	75	]	(66.7%)
Effective	43 (27.4%)	8 (25.0%)	51	]	
Slightly effective	17 (10.8%)	4 (12.5%)	21	]	(23.3%)
No response	28 (17.8%)	14 (43.8%)	42	]	
	157	32	189	patients	

Table 9 Therapies Combined with ESWL

	common bile duct stones (157 patients)	intrahepatic stones (32 patients)
ESWL alone	47	5
EST	70	12
Surgery	13	5
PTCSL	7	8
Oral litholytic agent	15	2
Direct litholytic agent	5	0

* Multipul answers were allowed for a single patients

32 patients at 1/4 of the institutions investigated (Fig. 1).

The results of ESWL for bile duct stones are shown in Table 8. For the evaluation of ESWL in the treatment of bile duct stones, disappearance of calculi was defined as "very effective," reduction of stone size to under 1 cm as "effective," and cracking of the stone as "slighly effective." Bile duct stones were eliminated by ESWL in 69/157 patients (44.0%).

Intrahepatic stones were eliminated by ESWL in 6/32 patients (18.7%). In general, calcium bilirubinate stones account for about 80% of intrahepatic stones, so it seems reasonable that ESWL produced no response in 14 patients (43.2%).

With regard to other procedures combined with ESWL in the treatment of bile duct stones, endoscopic sphincterotomy (EST) or PTCSL was performed as an adjuvant therapy in most patients. Bile duct or intrahepatic stones were treated with ESWL alone in 52 patients (52/189; 27.5%). Surgery was performed in the patients with no response to ESWL (Table 9).

Discussion

In the treatment of biliary stones, not only accurate detection of the stone but also qualitative assessment of its composition is now possible owing to marked advances in imaging diagnosis and therefore physicians can select the correct therapeutic approach on an informed basis.

In 1982, Chaussy et al. first introduced ESWL to urology, using it for the fragmentation of kidney stones[2]. Four years later, Saurebruch et al. applied ESWL to the treatment of gallstones. At that time, they set the indications for ESWL as (1) gallstones <30 mm in diameter, (2) solitary radiolucent stones. Or (3) less stones equal in volume to a solitary stone satisfying the above conditions[1].

The present nationwide survey showed that ESWL was employed for the treatment of gallstones

at relatively high frequency (27.4%), possibly because institutions actively employing ESWL were investigated in this survey.

The present survey also indicated that the possibility of complete resolution is limited to solitary stones less than 20 mm in diameter. In consideration of the widespread use of laparoscopic cholecystectomy which has increased dramatically during the past 3 years, it seems likely that there may be a great change in the therapeutic approach to gallstones in the future and a decrease in the use of ESWL. The indications for ESWL may decrease in the future, because (1) the system is expensive and complex to operate, (2) the stones which can be treated with ESWL are limited to cholesterol calculi, (3) the duration of treatment may be prolonged, (3) the duration of treatment may be prolonged, (4) complications like cholecystitis or pancreatitis may occur, (5) the recurrence rate is 40–70% and the 1-year recurrence rate is 15–20%[3], and (6) oral litholytic therapy usually needs to be performed in combination[4].

ELEWAUT et al. studied 693 patients and reported that complete resolution could be achieved by ESWL in 84% of patients with solitary stones which were radiolucent and were below 20 mm in diameter, while the cure rate decreased sharply in other cases. They also insisted that the indications for ESWL should be determined on the basis of treatment duration and cost[5].

On the other hand, ESWL has the following merits: (1) no incision is needed although transient redding of the skin occurs and (2) only an analgesic agent is used without general anesthesia being necessary. Thus, ESWL can be performed on an ambulatroy basis. In addition, ESWL has been used to treat common bile duct stones in some institutions.

ZIEGENHANGEN et al. reported that laparoscopic cholecystectomy could more easily be performed for large gallstones if adjuvant ESWL is done 2–48 hr earlier, since edema was produced in the subserosa[6].

VERGUNST et al. suggested from an in vitro study that the CT value is more useful than radiolucence as the basis of setting the indications for ESWL, and stated that a CT value below 110 HU indicated a pure cholesterol stone in over 95% of cases. They therefore suggested that it is most appropriate to use ESWL for patients with CT values below 110 HU[7].

NITSHE et al. studied the composition of calculi and the type of fragments. They suggested that calculi formed of at least 97% cholesterol produced fragments about 1 mm in size that could be dissolved completely. In contrast, when the cholesterol content is 64–94% the calculi usually break into 4–5 large even fragments that rarely disssolve completely[8].

In the present survey, the mean number of ESWL sessions required to achieve complete resolution was 3.6 in the 1,021 patients with complete resolution of their stones. The stones disappeared before the third ESWL session in 68.3% of these patients. Thus, alternative therapy may have to be considered if no response is observed after the third session of ESWL therapy.

After ESWL, recurrence occurs in 15–20% of patients within 1 year of complete resolution[2]. Recurrence of gallstones is usually detected by ultra-sound or CT scanning. BRAKEL et al. indicated that remnant calculi under 5 mm in diameter were present in 50% or less of the patients with recurrent gallstones after complete resolution[9].

However, the risk of recurrence was taken into consideration at most institutions and bile acid preparations such as UDCA and CDCA were usually prescribed after ESWL. According to SCHNEIDER et al., complete resolution of gallstones is more common and recurrence is less frequent when the gallbladder volume is 80 ml or less. However, in patients with gallbladders larger than 80 ml, bile is retained and its viscosity increase in association with an increased recurrence rate[10]. In

addition, the frequency of complete resolution is lower and the recurrence rate is higher when the percent contraction of the gallbladder is under 50%[11]. Thus, it is necessary to keep the gallbladder contracted in order to increase the success rate of ESWL therapy and decrease the recurrence rate.

ESWL has also come to be used for the treatment of intrahepatic and bile duct stones since this application was first reported by BECKER et al. in 1987[12]. ESWL is thought to be particularly appropriate for patients with severe liver cirrhosis or elderly patients aged over 80 years in whom general anesthesia and surgery should perferably be avoided due to its high risk. Recently, cholesterol calculi have formed an increasing percentage of bile duct stones instead of calcium bilirubinate calculi, and cholesterol calculi now also account for 20% of intrahepatic stones. These are other factors supporting the value of ESWL. In the present series, common bile duct stones and intrahepatic stones were eliminated or broken into 1-cm or smaller fragments (i.e., ESWL was effective) in 126/189 patients (66.7%). BLAND et al. reported a fragmentation rate of 94.6% in 42 patients[1a]. However, common bile duct stones and intrahepatic stones can rarely be completely treated with ESWL alone and EST or PTCSL is usually performed after ESWL to eliminate the fragments from the bile duct.

BINMOELLER et al. reported a stone elimination rate of 95% or higher by combining such adjuvant therapy with ESWL in 741 patients with bile duct stones[14]. Intrahepatic stones are more common in Taiwan and ESWL has also been applied for the treatment of intrahepatic stones in that country. KER et al. of Taiwan performed an in vitro study which showed that stones filling the bile ducts are more difficult to fragment than mobile stones. Thus, they concluded that ESWL is not indicated for the treatment of extensive intrahepatic stones[15].

Currently, surgical treatment such as partial hepatectomy remains the primary approach for the treatment of intrahepatic stones. However, the incidence of postoperative remnant stones and the recurrence rate are both about 20%, so surgery cannot be considered to be the ideal therapy for intrahepatic stones.

Acetyl-cysteine (Mucofilin®) is a new intrabiliary litholytic agent that dissociates the s-s bonds of mucoproteins in gallstones, and is under investigation at present[16]. In the future, more new noninvasive treatments may be available for combination with ESWL in addition to EST and PTCS.

Conclusions

To assess the present status of ESWL for gallstones, a nationwide survey as performed by questionnaire. The results obtained were as follows:

1. ESWL was performed in 2,760 of 10,058 patients with gallstones (27.4%) during a period of 2.5 years. Gallstones were completely eliminated in 1,021 of these 2,760 patients (37.0%).
2. ESWL was significantly more effective for solitary stones less than 20 mm in diameter.
3. ESWL was also pplied for the treatment of common bile duct stones in 157 patients up to October 1992, achieving a cure rate of 44.0%.
4. ESWL was also performed for intrahepatic stones in 32 patients, with a cure rate of 18.7%.

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和文抄録

日本における体外衝撃波結石破砕装置 (ESWL) を用いた胆石治療の現状 —全国アンケート調査より—

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体外衝撃波結石破砕装置 (ESWL) を用いた胆石治療の実態を把握するために，ESWL の設置された全国251施設を対象としたアンケート調査を行い，50施設から回答を得た．

調査期間は各施設の ESWL 導入時から1992年10月までで，各施設の10,058例の胆嚢結石に対し，ESWL 治療は27.4％に行われた．その治療効果は ESWL 施行2,760例中，完全消失が1,021例37.0％もあり，完全消失例を得るための必要条件は，個数は 1 個で，最大径は 20 mm 以下であることが判明した．

肝内・総胆管結石に対する ESWL 治療では，総胆管結石は157例中44.0％が消失，肝内結石32例に対しても18.7％が完全消失し，今後の保存的治療法の一つとして期待される．